Application Note ▪ Medical

CINCINNATI TEST SYSTEMS

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How to Leak Test Medical One-Way Check Valves

Check or one-way valves allow liquid flow in one direction and resist reflux, or back-flow, in the opposite direction based upon the presence of an internal elastomeric “duckbill” valve or an elastomeric disc. This elastomeric valve is often housed in an injection-molded polymer/plastic body which is either ultrasonically welded or adhesively bonded.

Check valves are manufactured in high volume on high-speed automated production lines and testing 100% of parts for the different potential failures is critical.

Solutions for Leak Testing One-Way Check Valves

Sentinel Blackbelt

Single channel instrument

Sentinel Blackbelt Pro

Multi-channel instrument with features that support 21 CFR Part 11 and EU Annex 11

Test Methods

The common method to leak test these valves is the use of dry compressed air pressure or vacuum decay at pressures ranging from -12 to 50 psig. The single channel Sentinel Blackbelt or multi-channel Blackbelt Pro pressure/vacuum decay instrumentation with multiple sequential ports per test channel enable this type of testing.

There are different tests that can be performed to detect potential part failures:

1. Anti-Reflux Valve Leak: verifies the backflow resistance of the one-way valve itself.

2. Body Weld Leak: assesses weld or adhesive joint between the two halves for the body for leakage.

3. Below Cracking Pressure Valve Leak: challenges the one-way valve to ensure it does not open or leak before it is subjected to a minimum cracking pressure.

4. Above Cracking Pressure Valve Opening Verification: checks the one-way valve opens when subjected to a higher pressure than the minimum cracking pressure.

5. Actual Cracking Pressure Test: determining the precise cracking pressure for each valve tested.

Following are examples of how each of these tests work.

1. ANTI-REFLUX VALVE LEAK

The user's automation seals the outlet of the check valve to be tested, often with a CTS CO30, CO31 or CO32 Connect using an FDA-approved medical grade seal. The inlet remains vented to atmosphere so that leaks backward through the valve are exposed. A Start signal is then sent to the test instrument and the pressure decay cycle begins.

Pressurization and Fill

Using regulated compressed air from one sequential test port, the instrument pressurizes the outlet of the check valve to the desired test pressure for a defined Fill time. This pressure is measured by the instrument's pressure transducer and compared to min/max limits, enabling it to detect improper pressure supply or gross leaks on the part.

Stabilization

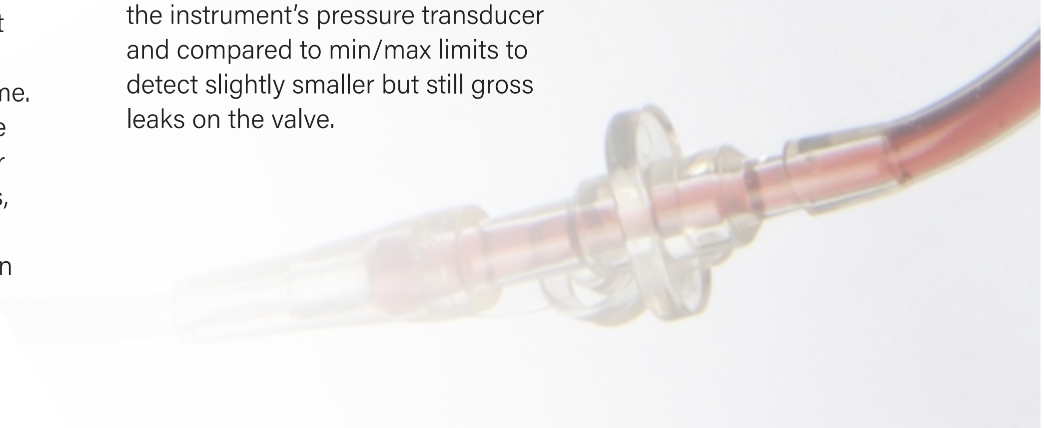
After Fill, the isolation valve inside the instrument closes, trapping pressure inside the part for a user-defined Stabilize time. This time is intended to minimize the natural pressure loss of even non-leaking parts due to expansion or creep, adiabatic thermal effect and potentially absorption, increasing the separation of the final measured pressure loss/decay between good parts and rejects.

The pressure is also measured by the instrument's pressure transducer and compared to min/max limits to detect slightly smaller but still gross leaks on the valve.

Test

After the Stabilize timer expires, the pressure transducer is tared, and the resulting pressure loss/decay is recorded over a defined Test time and compared to min/max pressure loss limits to determine whether fine leaks are present.

Once the Test cycle is complete, the pressure trapped inside the valve is vented to the atmosphere for a defined Exhaust time.



Using Leak Rate to Simplify Testing

Many manufacturers opt to convert the basic pressure decay/loss value to a leak rate in standard cubic centimeters per minute (sccm). Because pure pressure loss values are dependent upon the volume under test, similarly constructed valves, which have different pressurized volumes (due to differences in valve size or test air line length/diameter variations on automation lines) will yield different pressure losses even if they are leaking at the same rate. With a fixed leak rate, larger volumes have lower pressure decay/loss values vs. smaller volume parts with the same leak.

The advantage is that once the user defines a target reject leak rate in sccm, they can often apply the same leak rate criteria to an entire family of similar products having differing internal volumes. Executing a simple program calibration teaches the instrument the typical decay of a non-leaking part alone and then repeated with the same non-leaking part but with a fixed leak standard added. The learning process allows the instrument to accurately convert any future resulting pressure loss to a true leak rate in sccm and make testing parts with unique volumes to have matching reject criteria.

2. BODY WELD LEAK TEST

The user's automation seals on both the inlet and outlet of the check valve to be tested, often with the same type of CTS Connects as for the anti-reflux testing.

Both inlet and outlet are pressured together to expose the entire welded or bonded body of the valve to the test pressure and provide the opportunity to leak out. This is done by adding additional diverter valves to route air to both inlet and outlet simultaneously from the same measurement channel.

If only the inlet was pressurized and the outlet sealed to atmosphere, when they reached a pressure equilibrium—provided test pressure was greater than cracking pressure—a tiny leak on the outlet may be invisible to the instrument. This would occur if the pressure differential from inlet to outlet was insufficient for the check valve to crack which would cause decay on the inlet as well.

The user's automation sends a Start signal to the test instrument and the pressure decay cycle begins. The instrument pressurizes both the inlet and outlet of the valve with regulated compressed air to the desired test pressure for a defined Fill time. The next steps are as described in the anti-reflux valve leak test.

3. BELOW CRACKING PRESSURE VALVE LEAK TEST

In this test, the user's automation seals on the inlet of the check valve to be tested, often with CTS Connects. The outlet is vented to the atmosphere so that leaks in the forward direction through the valve are exposed.

Once the pressure decay test cycle begins the instrument pressurizes only the inlet with regulated compressed air to the desired test pressure within the Fill time. The rest of the test is as described in the previous examples.

4. ABOVE CRACKING PRESSURE OPENING VERIFICATION TEST

Like the Below Cracking Pressure Valve Leak Test, the automation seals on the inlet of the valve under test and the outlet is vented to atmosphere. For this test, an inverted-limit pressure decay test cycle is initiated.

Only the valve inlet is charged with pressure during the Fill time. Stabilization time is set to a bare minimum value (0.05 seconds) to minimize pressure losses through good, unblocked parts.

After the Stabilize time, the pressure transducer is tared and the resulting pressure loss/decay over a fixed time is recorded and compared to min/max pressure loss limits to determine whether or not the valve indeed remained cracked during the Test. Test time is short, between 0.1 and 1.0 seconds to permit 50-80% of the initial starting pressure seen during Fill time to be lost on parts with properly cracked valves.

At the end of the Test, the pressure inside the valve is vented to atmosphere for a defined Exhaust time. Then the final variable test result data are displayed on the instrument to make it obvious which parts have passed or failed.

5. ACTUAL CRACKING PRESSURE TEST

There is often the need to determine the precise cracking pressure for each valve tested. This is typically performed in offline audit test situations due to the nature of the test and extended text cycle time required.

Both the inlet and outlet of the check valve are sealed. CTS Connects are often used. While only the inlet is pressurized, the outlet is mated to an additional port on the Sentinel instrument where a downstream mass flow transducer awaits any user-defined rise in flow above 0.00 sccm, indicating flow is present on the outlet and the valve has obviously cracked.

Once the Start signal has been sent to the test instrument, the ramp to downstream flow event test cycle begins. Only the valve inlet is charged with pressure at a defined ramp rate throughout the Test time and the test pressure is measured by the upstream pressure transducer inside the instrument. Typically, at some point during the Test, the downstream mass flow transducer detects a sudden rise in flow coming through the valve from inlet to outlet, indicating the valve has cracked. At that moment, the instrument records the resulting measured pressure on the inlet of the valve and compares that pressure to the min/max pressure limits to determine whether the check valve cracked at the correct pressure.

The ramp may be set in several ways depending upon the instrument configuration.

If equipped with a mechanical pressure regulator, test air is routed through a precision Vernier mechanical flow restrictor (lockable), which may be set by the user to determine the ramping rate from 0.00 psig upward through the Test time.

If equipped with an electronic regulator, the following controls are possible:

- *Starting Pressure*: The electronic regulator can be user-programmed to start at some pressure above 0.00 psig to allow skipping pressures well below the expected cracking level, shortening the test.
- *Digital Ramp Rate*: The regulator can be user-programmed to increase pressure to the inlet of the valve at a defined rate controlled by the regulator digitally as opposed to requiring mechanical intervention.
- *Mechanical Ramp Rate*: It can use a combined user-programmed Starting Pressure and have it remain fixed throughout the test and route air through the Vernier mechanical flow restrictor to set the ramping rate, acting similarly to how a mechanical pressure regulator would be used to ramp.
- *Hybrid Ramp Rate*: The electronic regulator can use a combined Digital Ramp Rate and precision Vernier mechanical flow restrictor to set the primary ramp digitally but smooth the incremental pressure by attenuating the fill just slightly using the mechanical restrictor.
- *Decline Ramp Rate*: The user has the option to perform an additional test to ramp from a higher pressure toward a lower pressure until a loss of flow pressure occurs and the instrument detects the closing pressure of the valve.

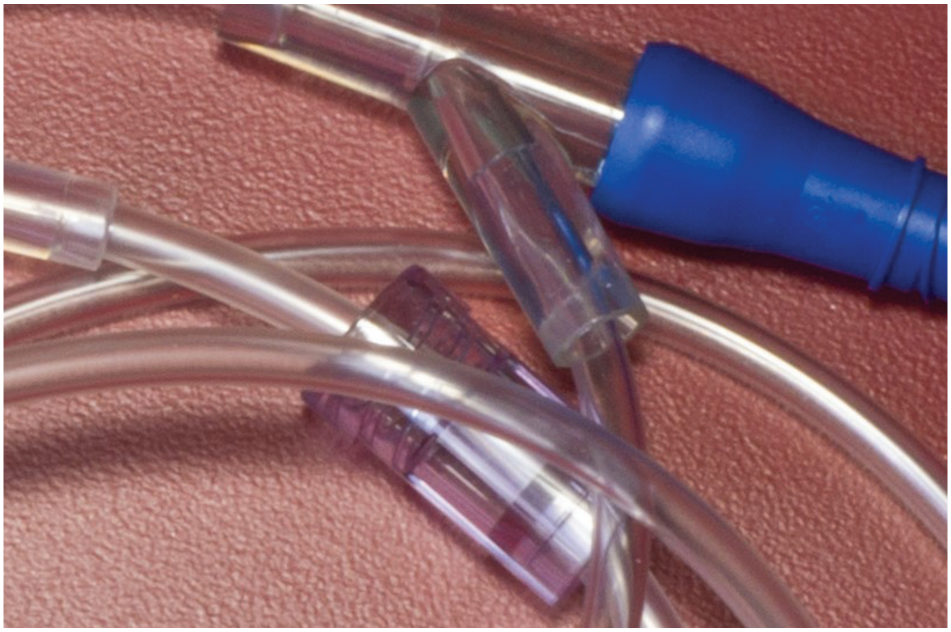
At the end of the Test, the air is vented to atmosphere and the variable test result data is displayed in the instrument panel to clearly indicate pass or fail.

Ensuring Failed Parts Are Properly Handled

If the above tests are manually executed using CTS Connect(s) driven by the Sentinel Blackbelt or Blackbelt Pro, the test program can be set to leave failed parts sealed by the Connect, forcing the user to either press a reset button or use a security key or password to release them. This method of forcing the operator to break rhythm limits the risk of failed parts being inadvertently placed for downstream operations.

Total test cycle time is dependent upon different factors, most importantly:

- Reject limit selected
- Volume of the pressurized/ evacuated area of the part under test
- Temperature stability of part and testing environment
- Dimensional stability of the part while under test
- Repeatability requirements defined by the user
- Accuracy, precision & resolution of the instrument executing the test
- Ramping rate needed for consistent cracking pressure detection



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